

REMARKS

Prior to the present amendment, claims 1 and 13 were under consideration, claims 2 and 14 were cancelled, and claims 3-12 were withdrawn from consideration. In the present amendment, applicants have added new claims 15-20. Accordingly, claims 1, 13, and 15-20 are currently under examination.

Interview

Applicants wishes to thank Examiner Fetterolf for the courtesy of a telephone interview on August 16, 2007 with the undersigned and Irving N. Feit. During the interview, the rejections raised in the office action mailed May 3, 2007 were discussed. A summary of the telephone interview is discussed below.

Rejection of claims 1 and 13 under 35 U.S.C. § 102(a) in view of Griswold, et al.

On page 3 of the office action, the examiner rejects claims 1 and 13 under 35 U.S.C. 102(b) for allegedly being anticipated by the Griswold et al. reference.

According to the examiner, Griswold et al. teach a method of treating chronic inflammatory disease in a mammal comprising administering an angiotensin II receptor antagonist at column 1, lines 66 to column 2, line 1. The examiner further states that "specifically, the patent teaches a method of treating disorders such as tumor growth, i.e., neoplastic transformation and growth or metastasis, at column 2, lines 6-12." The examiner then cites Griswold et al. for teaching that angiotensin antagonists include the AT1 antagonist, losartan, at column 3, lines 14-17.

The examiner concludes with the following: "In other words, the Examiner recognizes that Griswold et al. *teach* a method of treating disorders such as tumor growth, i.e., neoplastic transformation and growth/metastasis (column 2, lines 6-12). As such, Griswold et al. anticipates the currently amended claims" (emphasis added).

The section of Griswold et al. referred to by the examiner, i.e., column 2, lines 6-12, states the following:

The observation of the presence of Angiotensin II receptors on synovial cells gives rise to the *speculation* that this tissue is reactive and proliferates in response to injury may reflect a broader role for angiotensin in the regulation of tissue injury, proliferation and differentiation. As such *this* would include treatment of disorders such as tumor growth, i.e., neoplastic transformation, and growth/metastasis, bone marrow maturation...(emphasis added).

Applicants respectfully disagree with the examiner's interpretation of the Griswold et al. reference. The Griswold et al. reference does not anticipate the claimed invention.

First, the Griswold et al. reference does not teach the claimed method for reducing formation, progression or metastasis of a neoplasm. At most, it *speculates* "...that this tissue (synovial cells) is reactive and proliferates in response to injury may reflect a broader role for angiotensin in the regulation of tissue injury, proliferation and differentiation." A speculation does not constitute a teaching.

Nowhere in the MPEP is there basis for an anticipation rejection based on speculation. In fact, MPEP § 2131 states: "To anticipate a claim, the reference must **teach** every element of the claim" (emphasis added). According to The American Heritage® Dictionary of the English Language: Fourth Edition (2000), the verb "teach" is defined as "To impart knowledge or skill." However, the verb "speculate" is defined as "To meditate on a subject; reflect."

The mere speculation in Griswold et al. does not properly substitute for the teaching that is required in MPEP § 2131 for an anticipation rejection. Accordingly, the Griswold et al. reference fails to anticipate the claimed invention for this reason alone.

Secondly, whatever it is that Griswold et al. speculates about, it is not understandable to one skilled in the art. For example, the last sentence of the above quote from Griswold et al. states: “As such *this* would include treatment of disorders such as tumor growth...” See column 2, lines 10-12.

Griswold et al. appears to suggest that something “include[s] treatment of disorders such as tumor growth.” What that something is, however, is a mystery. More importantly, what the treatment would be is also a mystery. Therefore, a person having ordinary skill does not learn from Griswold et al. what “...would include treatment of disorders such as tumor growth...”

The presently claimed invention is a method for reducing formation, progression or metastasis of a neoplasm by administering an effective amount of an AT1 antagonist. Whatever it is Griswold et al. speculates about, there is not the remotest suggestion of such a method. If the examiner maintains this rejection, he is respectfully requested to point out precisely where in Griswold et al. such speculation may be found.

To summarize applicants’ argument in rebuttal to the rejection under §102 (b), an anticipating reference must “*teach*” the invention. See MPEP § 2131. Griswold et al. does not teach anything relating to tumors, it merely speculates about something.

And whatever it is Griswold et al. speculates about, it is incomprehensible. It is not sufficient to point to the incomprehensible speculation in Griswold et al. and assert that a person having ordinary skill could glean the claimed invention from the resulting gobbledygook.

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For the foregoing reasons, applicants respectfully request that the rejection of the claims under 35 U.S.C. § 102(b) over Griswold et al. be reconsidered and withdrawn.

Double Patenting Rejection

The examiner rejected claims 1 and 13 for non-statutory double patenting over claims 1-3, 5-8, and 10 of U.S. Patent No. 6,641,811.

Applicants will address this rejection for non-statutory double patenting with terminal disclaimers, if appropriate, upon notification of patentable subject matter in the present application. The examiner is respectfully requested to withdraw, at least temporarily, this rejection for non-statutory double patenting until he indicates the presence of otherwise allowable subject matter.

New Claims

New claims 15-19 more clearly distinguish the claimed invention from Griswold et al. Claims 15-16 and 18-19 further define the human to be treated by the claimed methods. Nowhere in Griswold et al., is there any disclosure of treating a transplant recipient or an autoimmune patient. Claim 17 further defines the type of neoplasm that is reduced by the claimed method. Nowhere in Griswold et al., is there any disclosure of reducing formation, progression, or metastasis of a neoplasm associated with immunosuppressive therapy.

Support for new claims 15-19 can be found, for example, on page 3, paragraphs [0013] and [0016], and on page 10, paragraph [0047]. New claims 15-19 were discussed with Examiner Fetterolf during the telephone interview with the undersigned on August 16, 2007.

The examiner's attention is also directed to new claim 20, which limits the neoplasm of claim 1 to specific tumors. Whatever Griswold et al. discloses about tumors in the above quote, which, as mentioned above, is not at all clear, relates only to synovial tissue ("The

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observation of the presence of Angiotensin II receptors on *synovial cells* gives rise to the speculation that *this tissue* is ...") The types of tumors recited in claim 20 are not those of synovial tissue. Support for new claim 20 is found in paragraph 15 of the specification, which bridges pages 3 and 4. Therefore, applicants believe claim 20 is independently patentable.

In view of the foregoing amendments and remarks, applicants respectfully request entry of the claim amendments and favorable consideration of claims 1, 13, and 15-20. If the examiner has any questions or concerns regarding this amendment, he is invited to contact the undersigned at the telephone number listed below.

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Respectfully submitted,

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